GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:407
ANSWERED ON:21.12.2005
REGULATION OF CLINICAL RESEARCH
Reddy Shri Magunta Sreenivasulu

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether some International scientific journals have recently raised doubts on the credibility of certain drug research work in India; and

(b) if so, the details of the steps proposed to be taken to regulate clinical research?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) and (b): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 407 FOR 21ST DECEMBER, 2005

No specific instance of International Scientific Journals raising doubts on the credibility of drug research in India has come to notice. However, some Indian authors had published an article in the New England Journal of Medicine Volume 352:1633-1636 dated April 21, 2005, wherein certain concerns were raised regarding adequacy of regulatory capacities to oversee the clinical trials in India, lack of trained clinical investigators and relevant infrastructure, absence of informed consent from study subjects, free supply of study medication to the patients after completion of trial, working of institutional review boards, and instances of unauthorized trials etc.

In another article published by another Indian author in a journal `Annals on oncology` dated 8th July, 2005, the recent measures taken by the Government to regulate clinical trials based on the principles on Good Clinical Practices (GCP) and the advantages to India in participating in multi-centric global trials for anti-cancer drugs have been appreciated.

In respect of regulation of clinical trials in India, Government has streamlined the provisions under Drugs and Cosmetics (D&C) Rules concerning conduct of clinical trials in the country. Rules 122A to E of the D&C Rules have been amended for this purpose laying down mandatory requirements for prior permission to conduct clinical trials and powers to withdraw a trial. The term `clinical trial` has been defined under the Rules. Schedule -Y under the Rules that prescribes the requirements for pre-clinical and clinical studies concerning new drugs has been extensively revised in January, 2005, to define the responsibilities of sponsors, clinical investigators and ethics committees. The requirements of GCP guidelines published by the Government have been made mandatory. Detailed requirements and procedures for obtaining informed consent of study subjects, including those who are illiterate, have been prescribed. Standard Operative Procedures (SOP) have been prescribed for different functions involved in conduct of clinical trials.

Phase-I clinical trial for the drug discovered/developed outside India has not been permitted to be conducted in the country except for those drugs that are of specific relevance to the country.

Steps have also been undertaken to arrange training programmes/Workshops through WHO support for various stakeholders involved in conducting clinical trials. This also includes capacity to undertake regulatory inspections of clinical trials in the country.